UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MARY K. JONES, Individually and on Behalf of All Others Similarly Situated, Plaintiff vs. PFIZER INC., et al., Defendants.	Civil Action No. 1:10-cv-03864-AKH CLASS ACTION SUPPLEMENTAL MEMORANDUM OF LAW IN SUPPORT OF REQUEST TO COMPEL TESTIMONY

I. INTRODUCTION

The parties' joint letter dated October 15, 2014 presented the Court with a dispute concerning plaintiffs' request to compel former Pfizer Inc. ("Pfizer" or the "Company") Regional Manager, Mary Holloway, to answer questions regarding her awareness of Pfizer's misbranding (more commonly known as "off-label promotion") of the drug Bextra. As the joint letter demonstrates, the basic facts here are not in dispute: (1) Pfizer stopped marketing Bextra over nine years ago; (2) Ms. Holloway stopped working for Pfizer over five years ago; (3) on June 29, 2009, following a guilty plea, Ms. Holloway was convicted of and sentenced for a one-count misdemeanor violation of the Food, Drug and Cosmetic Act, 21 U.S.C. §§331(a), 333(a)(1) and 352(f), relating to her role in Pfizer's off-label promotion of Bextra; (4) Ms. Holloway's conviction became final on or about July 13, 2009; (5) Ms. Holloway previously appeared for a deposition in this matter and refused to answer any questions about her past employment at Pfizer, including her activities related to the promotion of Bextra; and (6) through counsel, Ms. Holloway has indicated her intention to persist in her Fifth-Amendment invocation as she did before.

Pursuant to the Court's Order Regulating Witness' Invocation of 5th Amendment (Dkt. No. 230), on October 24, 2014, plaintiffs provided Ms. Holloway with a list of subjects on which they propose to question her. Plaintiffs attached to this list 43 documents about which they propose to question Ms. Holloway. The government possessed all of these documents by the time Ms. Holloway was sentenced for her role in Pfizer's off-label promotion of Bextra. Plaintiffs have assured Ms. Holloway that Bextra is the only drug about which they will ask any questions. As for the documents that plaintiffs provided to Ms. Holloway, she or her counsel authored all but a few of them. Most of these documents are emails that Ms. Holloway sent or received about 10 years ago, and plaintiffs have assured Ms. Holloway that their questions concerning these documents will be

limited to the portions relating to Bextra. One of the most important documents about which plaintiffs wish to question Ms. Holloway is her own sentencing memorandum, which she filed publicly on June 12, 2009, attached hereto as Ex. 1.

Given the passage of time, the finality of Ms. Holloway's Bextra-related conviction, and plaintiffs' agreement to limit their examination of Ms. Holloway to Bextra-related questions and Bextra-related documents that the government possessed when Ms. Holloway was sentenced over five years ago, Ms. Holloway has no reasonable basis to fear that her answers to plaintiffs' questions will expose her to new criminal liability. Accordingly, plaintiffs respectfully request that the Court compel Ms. Holloway to answer questions concerning the subjects and documents that plaintiffs provided to her on October 24, 2014.

II. RELEVANT FACTS

The list of subjects plaintiffs provided to Ms. Holloway on October 24, 2014 consisted of the following:

> Beyond very brief and basic background questions regarding her positions with Pfizer and her responsibilities as Regional Manager (including the Pfizer employees below and above her in her chain of command), we intend to limit our questioning of Ms. Holloway to Bextra-related questions. As you know, Bextra has been off the market for over nine years, and we will not ask Ms. Holloway any questions about any other drugs.
>
> Specifically, we will ask Ms. Holloway about Bextra promotional methods (*e.g.*, treating DVT, adding to hospital/surgical protocols, using Pfizer-paid doctors, etc.), Bextra-related document deletion and alteration (*e.g.*, what and how she learned about it, to whom she reported it, Pfizer's response to her, etc.), the substance of her interviews with Pfizer's lawyers concerning Bextra (*e.g.*, what they asked, what she disclosed, etc.), and the termination of her employment with Pfizer (*e.g.*, whether Pfizer's explanation included any mention of Bextra, severance package, etc.).
>
> All of our substantive questions will relate to documents, most of which were authored or received by Ms. Holloway. Rather than summarize each document, I am attaching them for your review and confirmation that you have had most of them for over a year (two (Exs. 419 and 425) are missing attachments, which I will send later if we have them; if you notice any other missing attachments, please let me know).

> These documents should provide all the detail you need regarding the subjects of our questions for Ms. Holloway. For example, in Ms. Holloway's sentencing memorandum, she informed the Court *inter alia* that all of her Bextra-related actions (*e.g.*, instructing others to promote Bextra for DVT and for hospital/surgical protocols) were consistent with instructions and guidance that she had received from Pfizer. We would like to ask about this and about her disclosure to Pfizer regarding her Bextra-related activities and guidance to her own subordinates. To put it bluntly, we have yet to see any indication that Ms. Holloway concealed from Pfizer any of her Bextra-related activities, and that is something we want to confirm. To the extent the attached documents include subjects that are not related to Bextra, we will not be questioning Ms. Holloway about those non-Bextra-related subjects or drugs.

As mentioned above, one of the most important documents about which plaintiffs wish to question Ms. Holloway is the sentencing memorandum that she publicly filed on June 12, 2009. A few brief quotes from this sentencing memorandum demonstrate the importance of Ms. Holloway's testimony to this case and the implausibility of her assertion of the privilege against self-incrimination regarding these statements (which are fully corroborated by other documents in this matter):

- "Ms. Holloway has the distinction of being one of the first five females at Pfizer to be promoted to the position of Regional Sales Manager. In that capacity, she supervised approximately 100 sales representatives, district managers and others in the Northeast Region of Pfizer's Powers Division." *See* Ex. 1 at 2.

- "In November 2001, the Food and Drug Administration ('FDA') approved Bextra to treat the signs and symptoms of osteoarthritis, adult rheumatoid arthritis, and primary dysmenorrhea, an acute premenstrual pain condition." *See id.* at 3.

- "The benefit to a company in having its product on a protocol or standing order is obvious, because the product becomes the medicine of choice for all patients to whom the instructions apply. The implementation of a marketing plan to obtain Bextra protocols and standing orders was a company-wide initiative, not a Northeast Region initiative, and certainly not a Mary Holloway initiative." *See id.* at 6-7.

- "In 2003, regional managers were required to track protocols obtained in their territory and report back to the Company. As such, and no differently from any other, Ms. Holloway's region dutifully reported Bextra protocols attained for orthopedic, podiatry, urology, ob/gyn, ENT and dental indications, where much of the usage was off-label. Corporate tracked this information, and at no time did it inform Ms. Holloway that any of the reported protocols were inappropriate. Instead, the instruction was to get more protocols. Indeed, to ensure compliance with its corporate message, Pfizer sales representatives and sales managers were

evaluated based on their ability to obtain protocols, and regions received positive recognition and public praise at Plan of Action ('POA') sales meetings for having obtained such protocols in their territory." *See id*. at 7.

- "[A]s part of her segment [at a national sales meeting], Ms. Holloway spoke about Bextra protocols in the perioperative setting, which included off-label uses. As a clear sign of corporate endorsement, two of Ms. Holloway's superiors complimented her for the presentation. Moreover, one Pfizer Medical Director in attendance wrote to another Medical Director that 'Mary Holloway was awesome' at the meeting. In accordance with Pfizer practice, Ms. Holloway forwarded adopted protocols to her regional sales force. This collection and dissemination of protocols was not limited to Ms. Holloway's Northeast region, but took place across the various sales regions. It was part of the Pfizer culture." *See id*. at 8.

Rather than inundate the Court with the remaining 42 documents about which plaintiffs wish to question Ms. Holloway, plaintiffs will bring to the October 30, 2014 hearing on this issue a full set of these documents for the Court's consideration.

III. ARGUMENT

A. Plaintiffs Wish to Limit Their Examination to the Same Facts, Circumstances and Crime Underlying Ms. Holloway's Spring and Summer 2009 Prosecution and Conviction

Plaintiffs are not looking to explore any areas with Ms. Holloway that were not part of her prior plea and conviction – and well known to the government at that time. It simply is not reasonable to suggest that answers to questions concerning the same exact information about which the government was aware, including information that Ms. Holloway herself provided, at the time of Ms. Holloway's plea and conviction could be used against her in a completely new prosecution based on the identical facts. Such a suggestion goes from unreasonable to completely implausible when one accounts for the passage of time since Ms. Holloway's acts (2002-2005), since her employment with Pfizer ended (2008), since Pfizer stopped marketing Bextra (2005) and since Ms. Holloway's Bextra-related conviction became final (July 2009). In light of the limited areas of inquiry for which plaintiffs seek to compel answers, it is apparent that the statute of limitations for any criminal prosecution has run:

> It is true as a general proposition that "if a prosecution for a crime, concerning which the witness is interrogated, is barred by the statute of limitations, he is compellable to answer." *Brown v. Walker*, 161 U.S. 591, 598 (1896). *See The Pillsbury Company v. Conboy,* 459 U.S. 248, 266 n.1 (1983) (Marshall, J., concurring); *Hale v. Henkel,* 201 U.S. 43, 67 (1906) ("If the testimony relate to criminal acts long past, and against the prosecution of which the statute of limitations has run, or for which he has already received a pardon or is guaranteed an immunity, the amendment does not apply"); *In Re Master Key Litigation,* 507 F.2d 292, 293 (9th Cir. 1974); *United States v. Stewart,* 445 F.2d 897, 900-01 (8th Cir. 1971); *United States v. Goodman,* 289 F.2d 256, 259 (4th Cir. 1961) ("Of course, if by reason of the statute of limitations there remains ***no possibility*** that a prosecution of the witness could result from or be assisted by his answers to questions, he is not justified in refusing to answer") (emphasis in original), *vacated on other grounds*, 368 U.S. 14 (1961); *United States v. Miranti,* 253 F.2d 135, 138 (2d Cir. 1958); *United States v. Rosen,* 174 F.2d 187, 191-92 (2d Cir. 1949), *cert. denied,* 338 U.S. 851 (1949).

United States v. Clark, No. 86-0288T, 1988 U.S. Dist. LEXIS 16868, at *14-*15 (W.D.N.Y. July 19, 1988).

It is the very nature of the Fifth Amendment itself that limits it so as to provide no shelter where the running of the statute of limitations eliminates the risk of prosecution for crimes related to a particular line of inquiry. "'The interdiction of the Fifth Amendment operates only where a witness is asked to incriminate himself – in other words, to give testimony which may possibly expose him to a criminal charge. But if the criminality has already been taken away, the Amendment ceases to apply.' *Hale v. Henkel,* 201 U.S. 43, 67 [(1906)]." *Ullmann v. United States,* 350 U.S. 422, 430-31 (1956). Because plaintiffs will not be eliciting any new information from Ms. Holloway and the statute of limitations has run on any crimes related to the old information, answers to plaintiffs' questions will not possibly expose her to a new criminal charge. Accordingly, the Fifth Amendment does not apply here.

B. An Order Compelling Ms. Holloway's Testimony Will Ensure that Her Testimony Cannot Be Used Against Her in Any Criminal Proceeding

An order compelling Ms. Holloway to testify is the ultimate backstop to ensure that her testimony will not be used against her in a criminal proceeding:

> As we reaffirmed last Term, a defendant's compelled statements, as opposed to statements taken in violation of *Miranda,* may not be put to any testimonial use whatever against him in a criminal trial. "But *any* criminal trial use against a defendant of his *involuntary* statement is a denial of due process of law." (Emphasis in original.) *Mincey v. Arizona,* 437 U.S. 385, 398 [1978].

New Jersey v. Portash, 440 U.S. 450, 459 (1979). As explained above, the lack of any new areas of inquiry and the running of the statute of limitations as to any crimes related to these old areas of inquiry eliminate any possibility of criminal exposure for Ms. Holloway due to her testimony. But if the Court wants to add suspenders to this amply secure belt, an order compelling her testimony will certainly get the job done. As the Supreme Court confirmed in *Portash*, a witness's compelled statements may not be put to any testimonial use whatever against her, including even impeachment. *Id.* Moreover, "the Fifth Amendment privilege against compelled self-incrimination extends to the exclusion of derivative evidence, *see United States v. Hubbell*, 530 U.S. 27, 37-38, 120 S. Ct. 2037, 147 L. Ed. 2d 24 (2000) (recognizing 'the Fifth Amendment's protection against the prosecutor's use of incriminating information derived directly or indirectly from . . . [actually] compelled testimony'); *Kastigar v. United States*, 406 U.S. 441, 453, 92 S. Ct. 1653, 32 L. Ed. 2d 212 (1972)." *United States v. Patane*, 542 U.S. 630, 646 (2004). Accordingly, an order compelling her testimony will assure that Ms. Holloway's testimony is never used against her in violation of the Fifth Amendment.

IV. CONCLUSION

For all the foregoing reasons, plaintiffs respectfully request that the Court compel Ms. Holloway to respond to questions limited to the subjects and documents set forth above and provided to Ms. Holloway on October 24, 2014.

DATED: October 28, 2014

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 28, 2014, I authorized the electronic filing of the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the e-mail addresses denoted on the attached Electronic Mail Notice List, and I hereby certify that I caused to be mailed the foregoing document or paper via the United States Postal Service to the non-CM/ECF participants indicated on the attached Manual Notice List.

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on October 28, 2014.

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